



## California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY  
DEPARTMENT OF CONSUMER AFFAIRS  
ARNOLD SCHWARZENEGGER, GOVERNOR

### LEGISLATION AND REGULATION COMMITTEE

#### Regulation Report

#### FOR ACTION

**Action Item 1 – The Legislation and Regulation Committee (committee) recommends that the board adopt the proposed regulation with changes made pursuant to a 15-day notice published on April 2, 2004. The proposed rulemaking contains non-controversial amendments to sections 1710, 1711, 1717.1, 1717.4, 1720, 1721, 1723.1, 1724, 1749, 1793, 1793.1, 1793.2, 1793.4, 1793.5, 1793.6, and 1793.7.**

Discussion: This rulemaking consolidates many non-controversial changes to board regulations. It was noticed without a hearing and no party requested a hearing. The board received no comments during the comment period. The text, initial statement of reasons and notice document are included in Attachment 1 for your information.

**Action Item 2 – Adopt the proposed regulation amending Section 1719 to permit a pharmacist to serve as pharmacist-in-charge at two pharmacies located within 50 miles of each other.**

Discussion: This rulemaking received only one comment during the comment period. A copy of that comment letter is included in Attachment 2 for your review. The text of the proposed regulation, the initial statement of reasons and notice document are included under the regulation hearing section for your information.

**Action Item 3 – Adopt the proposed regulation amending Section 1793.3 to eliminate the clerk/typist ratio.**

Discussion: This rulemaking received only one comment during the comment period. A copy of that comment letter is included in Attachment 2 for your review. The text of the proposed regulation, the initial statement of reasons and notice document are included under the regulation hearing section for your information.

#### NO ACTION

#### Regulation Update

#### Regulation Review

The board submitted and had its regulation review reports approved by the administration in February. The administration also approved the board moving forward with the sterile compounding regulations which had been held in abeyance pending completion of the regulation review process. That rulemaking file was

submitted to the Office of Administrative Law (OAL) on March 8, 2004. The board is still waiting for a signed fiscal impact form which is needed before the regulation can be approved.

## **Rulemaking Activity**

Staff published three rulemaking notices in February. The first notice consolidated a substantial number of non-controversial regulation changes in a single large filing to reduce the volume of paperwork required. This notice was published on February 13, 2004 and was noticed without a hearing and no interested party has requested a hearing. This package will be on the agenda for a board vote at the April 2004 board meeting. The board received no comments on this regulation package. Staff published a 15 day notice to make a minor change to the language permitting the board to release a scaled score to examinees. That notice period ends April 19, 2004 and the board can vote on the regulation in its final form at the April 2004 board meeting.

Staff published two remaining regulation proposals (PIC at two locations, elimination of the clerk/typist ratio) separately on February 20, 2004. Both of these proposals may have opposition, and they were noticed separately to allow the board flexibility in disposing of these proposals. Both regulations were noticed for a hearing at the April 2004 board meeting.

With the publication of these three notices, most of the rulemaking backlog has been addressed. A regulation to update the board's pharmacy self-assessment form still remains to be taken up. This regulation will be acted on as staff resources permit. Staff will also compile a Section 100 rulemaking later this year to make technical and clean-up changes to our regulations in light of recent legislation.

## **Pending Regulations**

### **Section 1709.1 - Pharmacist-in-Charge at Two Locations**

Summary: This regulation will permit a pharmacist to serve as pharmacist-in-charge at two locations.

Status: Rulemaking Notice Published February 20, 2004.

### **Section 1710 – Hospital Central Fill**

Summary: This regulation will permit central refill operations for hospitals.

Status: Rulemaking notice published February 13, 2004.

### **Section 1711 – Patient Notification**

Summary: This regulation will clarify patient notification requirements in the event there is a medication error.

Status: Rulemaking notice published February 13, 2004.

### **Section 1717.1 – Common Electronic Files**

Summary: This regulation requires pharmacies using common electronic files to adopt policies ensuring patient confidentiality.

Status: Rulemaking notice published February 13, 2004.

### **Section 1717.4 – Authentication of Prescriptions**

Summary: This regulation will require pharmacists to ensure the authenticity of prescriptions.

Status: Rulemaking notice published February 13, 2004.

**Section 1720 – Pharmacist License Process**

Summary: This regulation will require pharmacists to pay the licensing fee in a shorter time frame and require applicants to take the examination within one year of applying.

Status: Rulemaking notice published February 13, 2004.

**Section 1721 – Pharmacist Exam**

Summary: This regulation will increase the penalties for cheating on the pharmacist licensure examination.

Status: Rulemaking notice published February 13, 2004.

**Section 1724 – Passing Score**

Summary: This regulation will revise the methodology of determining the passing score on the pharmacist licensure examination to comply with changes made by Senate Bill 361.

Status: Rulemaking notice published February 13, 2004.

**Sections 1749 & 1793 et seq. – Pharmacy Technicians**

Summary: This regulation conforms and clarifies regulations relating to pharmacy technicians to reflect changes made by Senate Bill 361.

Status: Rulemaking notice published February 13, 2004.

**Section 1751 – Sterile Compounding**

Summary: This regulation will establish guidelines for the compounding of sterile drug products.

Status: Submitted to OAL March 8, 2004.

**Section 1793.3 – “Clerk-Typist” Ratio**

Summary: This regulation will eliminate the clerk/typist ratio.

Status: Rulemaking Notice Published on February 20, 2004.

**Awaiting Notice****Section 1715 – Pharmacy Self Assessment**

Summary: This regulation will update the pharmacy self assessment form to reflect recent changes in pharmacy law.

Status: Informational Hearing Required

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# *Attachment 1*

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**Board of Pharmacy  
Proposed Amendments  
Title 16, Part 17**

**Amend Section 1710:**

1710. ~~Inpatient~~ Hospital Pharmacy.

(a) For purposes of Business and Professions Code Section 4111, an inpatient hospital pharmacy is a hospital pharmacy pursuant to Business and Professions Code Section 4029 which solely or predominantly furnishes drugs to inpatients of that hospital. A hospital pharmacy which predominantly furnishes drugs to inpatients of that hospital may furnish drugs to outpatients or employees of that hospital or to walk-in customers, provided that sales to walk-in customers do not exceed one (1) percent of all the pharmacy's prescriptions.

(b) A hospital pharmacy may process an order for filling patient cassettes by another pharmacy within this state, provided:

- (1) The pharmacy that is to fill the cassettes either has a contract with the ordering hospital pharmacy or has the same owner as the ordering inpatient hospital pharmacy.
- (2) The filled cassette is delivered directly from the filling pharmacy to the ordering hospital pharmacy.
- (3) Each cassette or container meets the requirements of Business and Professions Code section 4076.
- (4) Both pharmacies are responsible for ensuring that the order has been properly filled.
- (5) Both pharmacies shall maintain complete and accurate records of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy.
- (6) Prescription information shall be electronically transferred between the two pharmacies.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4029, 4111, 4118 and 4380, Business and Professions Code.

**Amend Section 1711:**

1711. Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

~~(c) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form. Unless the pharmacist has already been notified of a medication error by the prescriber or the patient, the pharmacist shall immediately communicate to the patient and the prescriber the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.~~

(c) (1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

1. the date, location, and participants in the quality assurance review;
2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
3. the findings and determinations generated by the quality assurance review; and,
4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.

(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

~~(i) This section shall become operative on January 14, 2002.~~

Authority cited: Section 4005, Business and Professions Code; and Section 2 of Chapter 677, Statutes of 2000. Reference: Section 4125, Business and Professions Code.

### **Amend Section 1717.1:**

#### **1717.1. Common Electronic Files.**

(a) For dangerous drugs other than controlled substances: Two or more pharmacies may establish and use a common electronic file to maintain required dispensing information. Pharmacies using



such a common file are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file.

(b) For controlled substances: To the extent permitted by Federal law, two or more pharmacies may establish and use a common electronic file of prescriptions and dispensing information.

(c) All common electronic files must contain complete and accurate records of each prescription and refill dispensed.

(d) Common electronic files as authorized by this section shall not permit disclosure of confidential medical information except as authorized by the Confidentiality of Medical Information Act (Civil Code 56 et seq.).

(e) Pharmacies maintaining a common electronic file authorized by this section shall develop and implement written policies and procedures designed to prevent the unauthorized disclosure of confidential medical information.

Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116 and 4117, Business and Professions Code and Sections 56.10 and 56.11 of the Civil Code.

#### **Amend Section 1717.4:**

##### **1717.4. Electronic Transmission of Prescriptions.**

(a) Except as otherwise prohibited by law, prescriptions may be transmitted by electronic means from the prescriber to the pharmacy.

(b) An electronically transmitted prescription which meets the requirements of this regulation shall be deemed to be a prescription within the meaning of Business and Professions Code section 4040.

(c) An electronically transmitted prescription order shall include the name and address of the prescriber, a telephone number for oral confirmation, date of transmission and the identity of the recipient, as well as any other information required by federal or state law or regulations. The prescriber's address, license classification and federal registry number may be omitted if they are on file and readily retrievable in the receiving pharmacy.

(d) An "interim storage device" means an electronic file into which a prescription is entered for later retrieval by an authorized individual. Any interim storage device shall, in addition to the above information, record and maintain the date of entry and/or receipt of the prescription order, date of transmission from the interim storage device and identity of the recipient of such transmission. The interim storage device shall be maintained so as to ensure against unauthorized access and use of prescription information, including dispensing information.

(e) A pharmacy receiving an electronic image transmission prescription shall either receive the prescription in hard copy form or have the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. Any hard copy of a prescription shall be maintained on paper of permanent quality.

(f) An electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice. This requirement shall not apply to orders for medications to be administered in an acute care hospital.

(g) Electronic equipment for transmitting prescriptions (or electronic transmittal technology) shall not be supplied or used so as to violate or circumvent Business and Professions Code section 4000 et seq., Health and Safety Code section 11150 et seq., or any regulations of the board.

(h) Any person who transmits, maintains or receives any prescription or prescription refill, orally, in writing or electronically, shall ensure the security, integrity, authenticity, and

confidentiality of the prescription and any information contained therein.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4019, 4040, 4071, 4072 and 4075, Business and Professions Code; and Section 11150, et seq., Health and Safety Code.

#### **Amend Section 1720:**

1720. Application for Examination and ~~Registration~~ Licensure.

- (a) An application for ~~the pharmacist licensure~~ examination shall be submitted on the form provided by the ~~board~~ Board, and filed with the ~~board~~ Board at its office in Sacramento ~~at least (60) days before the date fixed for examination.~~
- (b) The fee required by section 1749, subdivision (d) ~~Section 1749(d)~~ shall be paid for each application for examination. The fee is nonrefundable.
- (c) An applicant who fails to pay the fee required by section 1749, subdivision (f) ~~Section 1749(f)~~ within ~~two years~~ one year after being notified by the ~~board~~ of his or her eligibility for a ~~certificate of registration license~~ as a pharmacist shall be deemed to have abandoned the application and must file a new application and meet all of the requirements which are in effect at the time of reapplication, ~~including retaking of the examination.~~
- (d) Each applicant shall be solely responsible for applying to and complying with the requirements imposed by the administrators of the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California for the administration of those examinations.
- (e) An applicant for examination whose eligibility is based on the provisions of Business and Professions Code Section 4200(a)(2)(b) and who does not fail to take the examination within five years one year of the date the applicant is determined by the board to be eligible to take the examination of filing the application shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements which are in effect at the time of reapplication.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

#### **Amend Section 1721:**

1721. Dishonest Conduct During Examination.

An applicant for ~~registration~~ examination as a pharmacist who engages in dishonest conduct during the examination shall not have ~~his or her that~~ examination graded, ~~and shall be denied the opportunity to take the examination at its next administration~~ not be approved to take the examination for twelve months from the date of the incident, and shall surrender his or her intern card until ~~such time as he or she takes the licensure~~ eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

### **Amend Section 1723.1:**

#### 1723.1. Confidentiality of Examination Questions.

~~Board of Pharmacy~~ Examination questions are confidential, ~~and any~~ Any applicant for any license, ~~permit or exemption certificate~~ issued by the ~~Board~~ board who removes all or part of any qualifying examination from the examination room or area, or who conveys or exposes all or part of any qualifying examination to any other person may be disqualified as a candidate for ~~the a~~ a license, ~~permit or exemption certificate for which the applicant applies.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections ~~4059-123~~ and ~~496 4200~~, Business and Professions Code.

### **Amend Section 1724:**

#### 1724. Passing Grade in Examination.

~~The pharmacist licensure examination consists of two sections, multiple choice and essay, both of which must be passed by achieving a score of 75 or more on each section. A candidate failing the multiple choice section shall be given a failing grade for the entire examination without regard to the performance on the essay section.~~

In order to pass the examination, an applicant shall be required to obtain a passing score as determined by a criterion-referenced method of establishing the passing point on each part of the examination.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

### **Amend Section 1749 as follows:**

#### 1749. Fee Schedule.

~~Effective July 1, 1999, the~~ The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with Section 4400 of the Business and Professions Code are hereby fixed as follows:

- (a) The fee for the issuance of a permit to conduct a pharmacy is three hundred forty dollars (\$340). The fee for the annual renewal of said permit is one hundred seventy-five dollars (\$175). The penalty for failure to renew is eighty-seven dollars and fifty cents (\$87.50).
- (b) The fee for the issuance of a temporary permit is one hundred seventy-five dollars (\$175).
- ~~(c) The fee for processing remodeling plans and inspecting the remodeled area is one hundred thirty dollars (\$130).~~
- (c) The fee for the issuance of a pharmacy technician license shall be fifty dollars (\$50). The fee for the biennial renewal of a pharmacy technician license shall be fifty dollars (\$50). The penalty for failure to renew a pharmacy technician license is twenty-five dollars (\$25).
- (d) The fee for ~~an applicant for~~ application and examination as a pharmacist is one hundred fifty-five dollars (\$155).
- (e) The fee for regrading an examination is seventy-five dollars (\$75).

- (f) The fee for the issuance of an original ~~certificate of registration as a pharmacist~~ license is one hundred fifteen dollars (\$115).
- (g) The fee for the biennial renewal of a pharmacist's license is one hundred fifteen dollars (\$115). The penalty fee for failure to renew is fifty-seven dollars and fifty cents (\$57.50).
- (h) The fee for the issuance or renewal of a wholesaler's permit is five hundred fifty dollars (\$550). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (i) The fee for the issuance or renewal of a hypodermic license is ninety dollars (\$90). The penalty for failure to renew is forty-five dollars (\$45).
- (j) The fees for a certificate of exemption under the provisions of sections 4053, 4054 and 4133 of the Business and Professions Code are as follows:
- (1) For the application and investigation ~~and examination~~ of the an applicant, the fee is seventy-five dollars (\$75).
  - (2) For the issuance or renewal of an original certificate for an application approved by the board the fee is one hundred ten dollars (\$110). The penalty for failure to renew is fifty-five dollars (\$55).
- (k) The fee for the issuance or renewal of a license as an out-of-state manufacturer or wholesaler is five hundred fifty dollars (\$550). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (l) The fee for registration as an intern pharmacist or extension of the registration is sixty-five dollars (\$65). The fee for transfer of intern hours or verification of licensure to another state is ten dollars (\$10).
- (m) The fee for the reissuance of any permit, license, certificate or renewal thereof, which has been lost, or destroyed or must be reissued because of name change, is thirty dollars (\$30). The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is sixty dollars (\$60).
- (n) The fee for registration and annual renewal of providers of continuing education is one hundred dollars (\$100). The penalty for failure to renew is fifty dollars (\$50).
- (o) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.
- (p) The fee for evaluation of an application submitted by a graduate of a foreign college of pharmacy or college of pharmacy not recognized by the board is one hundred sixty-five dollars (\$165).
- (q) The fee for the issuance of a clinic permit is three hundred forty dollars (\$340). The fee for the annual renewal of said permit is one hundred seventy-five dollars (\$175). The penalty for failure to renew is eighty-seven dollars and fifty cents (\$87.50).
- ~~(r) The fee for the issuance of a permit for a medical device retailer is three hundred forty dollars (\$340). The fee for the annual renewal of said permit is one hundred seventy-five dollars (\$175). The penalty for failure to renew is eighty-seven dollars and fifty cents (\$87.50).~~
- ~~(s)~~ The fee for the issuance of a permit for a warehouse of a medical device retailer is one hundred seventy dollars (\$170). The fee for the annual renewal of said permit is eighty-seven dollars and fifty cents (\$87.50). The penalty for failure to renew is forty-three dollars and seventy-five cents (\$43.75).

Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, ~~4130~~, 4196, 4200(c), 4400(a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (q), (r), (s), (t), (u), (v), (w), 4401 and 4403, Business and Professions Code.

### **Amend Section 1793:**

#### 1793. Definitions.

“Pharmacy technician” means an individual who, under the direct supervision and control of a ~~registered~~ pharmacist, performs packaging, manipulative, repetitive, or other nondiscretionary tasks related to the processing of a prescription in a ~~licensed~~ pharmacy, but who does not perform duties restricted to a ~~registered~~ pharmacist under section 1793.1.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

### **Amend Section 1793.1 as follows:**

#### 1793.1. Duties of a ~~Registered~~ Pharmacist.

Only a ~~registered~~ pharmacist, or an intern pharmacist acting under the supervision of a ~~registered~~ pharmacist, may:

- (a) Receive a new prescription order orally from a prescriber or other person authorized by law.
- (b) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.
- (c) Identify, evaluate and interpret a prescription.
- (d) Interpret the clinical data in a patient medication record system or patient chart.
- (e) Consult with any prescriber, nurse or other health care professional or authorized agent thereof.
- (f) Supervise the packaging of drugs and check the packaging procedure and product upon completion.
- (g) ~~Be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.~~
- ~~(h) Perform any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform.~~
- (i) Perform all functions which require professional judgment.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

### **Amend Section 1793.2 as follows:**

#### 1793.2. Duties of a Pharmacy Technician.

~~Pharmacy technicians may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting, and while under the direct supervision and control of, a registered pharmacist.~~

“Nondiscretionary tasks” as used in Business and Professions Code section 4115, include:

- (a) removing the drug or drugs from stock;

- (b) counting, pouring, or mixing pharmaceuticals;
- (c) placing the product into a container;
- (d) affixing the label or labels to the container;
- (e) packaging and repackaging.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.  
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

#### **Repeal Section 1793.4:**

##### **1793.4. Qualifications for Registration as a Pharmacy Technician.**

~~Except for the preparation of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility, no person shall act as a pharmacy technician without first being registered with the board. The board shall issue a certificate of registration to an applicant who has met any of the following requirements:~~

- ~~(a) Has obtained at least an associate of arts degree in one or more fields of study directly related to the duties performed by a pharmacy technician. Directly related fields of study include: health sciences, biological sciences, physical sciences, or natural sciences.~~
- ~~(b) Has successfully completed a training course specified by the board.~~
- ~~(c) Is eligible to take the board's pharmacist licensure examination.~~
- ~~(d) Has at least one year's experience, to include a minimum of 1,500 hours, performing the tasks specified in section 1793.2 while employed or utilized as a pharmacy technician to assist in the preparation of prescriptions for an inpatient of a hospital, for an inmate of a correctional facility, or other experience deemed equivalent by the board.~~
- ~~(e) A person possesses "experience deemed equivalent by the board" within the meaning of subdivision (d), if he or she has at least 1,500 hours of experience performing the duties specified in section 1793.3 in a pharmacy in the last three years, or has been employed for at least 1,500 hours as a pharmacy technician in another state or by the federal government.~~

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.  
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

#### **Amend Section 1793.5:**

##### **1793.5. Pharmacy Technician Application. ~~for Registration.~~**

The application for ~~registration~~ (Form 17A-5 Rev. 9/94) as a pharmacy technician license required by this section is available from the Board of Pharmacy upon request.

- (a) Each application for registration as a pharmacy technician shall include:
  - (1) Information sufficient to identify the applicant.
  - (2) A description of the applicant's qualifications ~~qualifying experience or education~~, and supporting documentation for those qualifications ~~that experience or education~~. ~~Examples of supporting documentation shall include: a certificate of completion issued by the training course provider showing the date of issuance and the number of theoretical and practical hours completed, transcripts, or an experience affidavit (Form 17A-6 or 17A-9 Rev. 9/94) signed by the pharmacist having direct knowledge of the applicant's experience.~~

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board ~~two completed fingerprint cards~~ and the fee authorized in Penal Code section 11105(e). In addition, a signed statement whether the applicant has ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state, or local ordinance.

~~(4) The registration fee shall be fifty dollars (\$50) effective July 1, 1995.~~

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days ~~whether if an~~ if an the application is ~~complete or~~ deficient; and what is needed to correct the deficiency. Once the application is complete, the board will notify the applicant within 60 days of a license permit decision.

(d) ~~Upon review and approval of the application, the board shall issue a certificate of registration as a pharmacy technician for at least one year. Before expiration of the a pharmacy technician license initial certificate of registration, a pharmacy technician must renew the that license by payment of the fee specified in Section 1749, subdivision (c). registration certificate with the board. Effective July 1, 1995, the fee is fifty dollars (\$50) and the penalty for failure to renew is twenty five dollars (\$25).~~

Authority cited: Sections 163.5, 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

**Amend Section 1793.6 as follows:**

**1793.6. Training Courses Specified by the Board.**

A course of training that meets the requirements of Business and Professions Code section 4202 ~~(a)(2) 1793.4(b)~~ is:

(a) Any pharmacy technician training program accredited by the American Society of Health-System Pharmacists,

(b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or

(c) Any other course that provides a training period of at least 240 hours of ~~theoretical and practical instruction covering at least the following; provided that at least 120 of these hours are in theoretical instruction in a curriculum that provides:~~

(1) Knowledge and understanding of different pharmacy practice settings.

(2) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.

(3) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.

(4) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

(5) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(6) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(7) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.  
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

**Amend Section 1793.7 as follows:**

**1793.7. Requirements for Pharmacies Employing Pharmacy Technicians.**

~~(a) Any pharmacy which employs a pharmacy technician shall do so in compliance with applicable federal and state laws and regulations governing pharmacy.~~

~~(b)~~

(a) Any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.

~~(c)~~

(b) Pharmacy technicians must work under the direct supervision of a ~~registered~~ pharmacist and in such a relationship that the supervising pharmacist is ~~on the premises at all times and is~~ fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

~~Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, a pharmacy technician may perform the duties, as specified in subdivision 1793.2, only under the immediate, personal supervision and control of a registered pharmacist and within the pharmacist's view.~~

~~(d)~~

(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.

~~(e)~~

(d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article ~~11~~ 12 of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.

(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.

(f) For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. Pursuant to Business and Professions Code section 4115(g)(1), this ratio shall not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.  
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.





**California State Board of Pharmacy**

400 R Street, Suite 4070, Sacramento, CA 95814-6237  
Phone (916) 445-5014  
Fax (916) 327-6308

STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GRAY DAVIS, GOVERNOR

April 2, 2004

**TO: ALL INTERESTED PARTIES**

**RE: PROPOSED AMENDMENT OF TITLE 16, SECTION 1724**

The board is proposing to amend text of the proposed regulation regarding patient privacy and internet dispensing. Changes to the originally proposed language are indicated in the accompanying text with double underline denoting additions and ~~double-strikeout~~ denoting deletions. These modifications are being made to the text that was noticed for a 45-day comment period that ended on March 29, 2004.

The board is required to make available the proposed language for at least 15 days. Written comments regarding the latest proposed amendments must be sent to the board postmarked no later than Monday, April 19, 2004.

Written comments should be sent to the board at:

Board of Pharmacy  
400 R Street, Suite 4070  
Sacramento, CA 95814  
Attn: Paul Riches

Comments may also be emailed to [Paul\\_Riches@dca.ca.gov](mailto:Paul_Riches@dca.ca.gov), or faxed to (916) 327-6308. Comments received by email or fax must contain the name and address of the commenter.

Attachment

#### **§1724. Passing Grade in Examination.**

~~The pharmacist licensure examination consists of two sections, multiple choice and essay, both of which must be passed by achieving a score of 75 or more on each section. A candidate failing the multiple choice section shall be given a failing grade for the entire examination without regard to the performance on the essay section.~~

In order to pass the examination, an applicant shall be required to obtain a passing score as determined by a criterion-referenced method of establishing the passing point on each part of the examination. The board may scale the passing score to 75 for the purpose of releasing scores to examinees.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

## **TITLE 16. Board of Pharmacy**

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on March 29, 2004.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 5 p.m. on March 15, 2004.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Sections 163.5, 851, 4005, 4007, 4038, 4075, 4114, 4115, and 4202 of the Business and Professions Code and to implement, interpret or make specific Sections 4005, 4007, 4019, 4027, 4029, 4038, 4040, 4050, 4051, 4052, 4071, 4072, 4075, 4112, 4114, 4115, 4116, 4117, 4120, 4125, 4196, 4200, 4202, 4400, 4401, and 4403 of the Business and Professions Code, Section 11150 et seq. of the Health and Safety Code, and Sections 56.10 and 56.11 of the Civil Code, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

### INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Section 163.5 of the Business and Professions Code authorizes specifies that delinquency fees for licenses issued by an agency within the Department of Consumer Affairs shall be fifty percent of the renewal fee.

Section 851 of the Business and Professions Code permits licensing boards within the Department of Consumer Affairs to require applicants to meet the standards of a private voluntary society or association.

Section 4005 of the Business and Professions Code authorizes the board to adopt rules and regulations for the protection of the public including the following:

- For the proper and more effective enforcement and administration of the Pharmacy Law
- Pertaining to the practice of pharmacy
- Pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed
- Providing for standards of minimum equipment for establishments licensed under this chapter

Section 4007 prohibits the board from adopting a regulation requiring a pharmacist from performing any duty that does not require a pharmacist's training.

Section 4019 of the Business and Professions Code defines "order" and specifies the care settings in which orders may be used to dispense or administer dangerous drugs or dangerous devices.

Section 4027 of the Business and Professions Code defines "licensed health care facility."

Section 4029 of the Business and Professions Code defines "hospital pharmacy."

Section 4038 of the Business and Professions Code defines "pharmacy technician."

Section 4040 of the Business and Professions Code defines "prescription."

Section 4050 of the Business and Professions Code declares the practice of pharmacy to be a profession.

Section 4051 of the Business and Professions Code prohibits the practice of pharmacy without a license.

Section 4052 of the Business and Professions Code specifies those professional services that a pharmacist may provide.

Section 4071 of the Business and Professions Code permits prescribers to authorize their agents to transmit prescriptions.

Section 4072 of the Business and Professions Code permits specified healing arts licentiates to transmit prescriptions authorized by a prescriber in specified care settings.

Section 4075 of the Business and Professions Code permits the board to adopt regulations designed to prevent the unauthorized furnishing of drugs.

Section 4112 of the Business and Professions Code requires non-resident pharmacies to register with the Board of Pharmacy.

Section 4114 of the Business and Professions Code permits the board to adopt regulations governing the activities of pharmacy interns.

Section 4115 of the Business and Professions Code specifies the activities that may be performed by a pharmacy technician.

Section 4116 of the Business and Professions Code specifies who may enter a pharmacy and grants the board authority to adopt regulations requiring security measures in pharmacies.

Section 4117 of the Business and Professions Code restricts access to a hospital pharmacy to certain personnel.

Section 4120 of the Business and Professions Code requires drug wholesalers to obtain a license from the Board of Pharmacy and makes declarations regarding non-resident pharmacies.

Section 4125 of the Business and Professions Code requires pharmacies to develop and implement quality assurance programs to reduce medication errors.

Section 4196 of the Business and Professions Code requires veterinary food-animal drug retailers to be licensed by the board.

Section 4200 of the Business and Professions Code specifies the requirements to become licensed as a pharmacist.

Section 4202 of the Business and Professions Code specifies the requirements to become licensed as a pharmacy technician.

Section 4400 of the Business and Professions Code specifies the fees for various licenses issued by the Board of Pharmacy.

Section 4401 of the Business and Professions Code requires pharmacists to renew their licenses every two years.

Section 4403 of the Business and Professions Code prohibits the board from specifies the requirements to become licensed as a pharmacist.

Section 11150 et seq. of the Health and Safety Code regulates the use and distribution of controlled substances.

Section 56.10 of the Civil Code requires patient consent prior to the disclosure of confidential medical information and establishes specific exceptions to that consent requirement.

Section 56.11 of the Civil Code establishes minimum standards for valid consent to disclose confidential medical information.

#### 1. Amend Section 1710

This proposal would permit hospital pharmacies to contract with other pharmacies to perform the centralized filling of drug orders dispensed in individual patient cassettes.

#### 2. Amend Section 1711

This proposal would require a pharmacist must notify the patient or prescriber of a medication only when the patient took the drug or the error results in a clinically significant delay in therapy.

#### 3. Amend Section 1717.1

This proposal would require pharmacies employing a common electronic file for prescription information to adopt policies and procedures to ensure that confidential medical information is only disclosed as permitted by the Confidentiality of Medical Information Act (Civil Code Section 56 et

seq.).

#### 4. Amend Section 1717.4

This proposal would require that any person who transmits, maintains or receives a prescription ensure the prescription's authenticity.

#### 5. Amend Section 1720

This proposal shortens the time a pharmacist applicant has to pay the required fee for licensure and specifies that applicants are responsible for compliance with requirements established by the administrators of the pharmacist licensure examination. This proposal also requires applicants for the pharmacist licensure examination to take the examination within one year of being determined to be eligible.

#### 6. Amend Section 1721

This proposal increases the penalties for cheating on the pharmacist licensure examination.

#### 7. Amend Section 1723.1

This proposal eliminates reference to the exemptee examination which is no longer required for an exemptee license.

#### 8. Amend Section 1724

This proposal revises the passing score on the pharmacist licensure exam to reflect changes made by Senate Bill 361 (Chapter 539, Statutes of 2003).

#### 9. Amend Section 1749

This proposal would incorporate fee provisions for pharmacy technicians that are deleted from Section 1793.5 in this proposed rulemaking, conform the pharmacist application fee to changes in Senate Bill 361 (Chapter 539, Statutes of 2003), deletes an obsolete reference to medical device retailers, and makes a number of technical and clarifying changes.

#### 10. Amend Section 1793

This proposal makes technical and clarifying changes to this section.

#### 11. Amend Section 1793.1

This proposal eliminates language incorporated in Section 1793.7 by this proposal, deletes a provision that is unnecessary, and makes technical and clarifying changes.

#### 12. Amend Section 1793.2

This proposal eliminates language that is duplicative of existing statute.

13. Repeal Section 1793.4

This proposal repeals this section as it is preempted by the passage of Senate Bill 361 (Chapter 539, Statutes of 2003) which specifies the qualifications for a pharmacy technician license in statute.

14. Amend Section 1793.5

This proposal amends the application requirements for a pharmacy technician to conform with changes made by Senate Bill 361 (Chapter 539, Statutes of 2003).

15. Amend Section 1793.6

This proposal amends pharmacy technician training program requirements to conform with changes made by Senate Bill 361 (Chapter 539, Statutes of 2003).

16. Amend Section 1793.7

This proposal eliminates provisions of the regulation that are duplicative of statutory provisions and incorporates a provision removed from Section 1793.1.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None

Business Impact:

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses:

The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business:

The Board of Pharmacy is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

#### EFFECT ON SMALL BUSINESS

The Board of Pharmacy has determined that the proposed regulations would not adversely affect small businesses. The proposed regulations provide greater flexibility to pharmacies and streamline application processes for certain license classifications.

#### CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

#### INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

#### TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the Board of Pharmacy at 400 R Street, Suite 4070, Sacramento, California 95814, or from the Board of Pharmacy website ([www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)).

#### AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

#### CONTACT PERSON



Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name: Paul Riches  
Address: 400 R Street, Suite 4070  
Sacramento, CA 95814  
Telephone No.: (916) 445-5014 x 4016  
Fax No.: (916) 327-6308  
E-Mail Address: Paul\_Riches@dca.ca.gov

The backup contact person is:

Name: Virginia Herold  
Address: 400 R Street, Suite 4070  
Sacramento, CA 95814  
Telephone No.: (916) 445-5014 x4005  
Fax No.: (916) 327-6308  
E-Mail Address: Virginia\_Herold@dca.ca.gov

Website Access: Materials regarding this proposal can be found at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).

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## **Board of Pharmacy**

### **Initial Statement of Reasons**

Subject Matter of Proposed Regulation: Hospital Central Fill, Patient Notification, Pharmacist Licensure, Pharmacy Technician Licensure, Fees, Common Electronic Files, and the Authenticity of Prescriptions

Sections Affected: 1710, 1711, 1717.1, 1717.4, 1720, 1721, 1723.1, 1724, 1749, 1793, 1793.1, 1793.2, 1793.4, 1793.5, 1793.6, and 1793.7

#### Specific Purpose of the Proposed Changes:

Proposed amendments to Section 1710 are designed to permit the filling of patient specific drug cassettes in a pharmacy located outside of the hospital in a manner analogous to that used by community pharmacies pursuant to Title 16, Section 1707.4 of the California Code of Regulations.

Proposed amendments to Section 1711 are designed to clarify when pharmacists must notify patients and prescribers of medication errors.

Proposed amendments to Section 1717.1 require pharmacies employing a common electronic prescription file to prevent unauthorized disclosure of confidential medical information and requires such pharmacies to develop written policies and procedures to ensure the confidentiality of private medical information.

Proposed amendment to Section 1717.4 requires pharmacists to ensure the integrity of a prescription.

Proposed amendments to Section 1720 requires applicants to submit their fee for licensure as a pharmacist within one year of passing the examination. The proposed amendments also require applicants to comply with requirements established by the administrators of the pharmacist licensure examination. Lastly, the time period allowed to take the examination is shortened to one year in conformity with the new examination requirements and shortens the time allowed to pay the fee for licensure to streamline board operations.

Proposed amendments to Section 1721 increases the penalty for dishonest conduct during examinations by prohibiting the applicant from retaking the examination for one year. The amendments also prohibit the issuance of a pharmacy technician license until the applicant is eligible to take the examination again.

Proposed amendments to Section 1723.1 eliminates references to the exemptee examination which is no longer required for licensure as an exemptee.

Proposed amendments to Section 1724 change the standard of passage for the pharmacist licensure examination.

Proposed amendments to Section 1749 are designed to eliminate obsolete fee provisions and to incorporate the fees for pharmacy technicians into this section.

Proposed amendments to Section 1793 eliminate obsolete language.

Proposed amendments to Section 1793.1 Section eliminate obsolete language and delete language that is incorporated elsewhere in a modest reorganization of pharmacy technician provisions.

Proposed amendments to Section 1793.2 eliminates language that is duplicative of language in existing statute.

Proposed repeal of Section 1793.4 eliminates provisions that are inconsistent with the qualifications for licensure as a pharmacy technician by Senate Bill 361 (Chapter 539, Statutes of 2003).

Proposed amendments to Section 1793.5 are designed to conform pharmacy technician application requirements to changes imposed by Senate Bill 361 (Chapter 539, Statutes of 2003) and to eliminate language that duplicates existing statutory provisions.

Proposed amendments to Section 1793.6 delete a requirement that training hours for pharmacy technicians be evenly split between theoretical and practical training.

Proposed amendments to Section 1793.7 eliminates language that that duplicates existing statutory provisions and to incorporate language deleted in other sections by this proposal as a modest reorganization of pharmacy technician provisions.

#### Factual Basis/Rationale

##### Section 1710

This proposal will increase the time hospital pharmacists can allocate to providing clinical and drug therapy management services by reducing the time that hospital pharmacists devote to dispensing activities. The proposal will also provide small, rural hospitals that do not have a full-time pharmacy service to increase patient safety and drug therapy management by subjecting medication orders to review by a pharmacist.

##### Section 1711

Existing regulations could be interpreted to require the redundant notification of patients and prescribers when a medication error occurs. The same regulations could also be interpreted to require patient notification of in a manner that inappropriately disrupts patient care. The proposed amendments preserve the patient notification requirement while providing practitioners with the flexibility to make that notification in the most appropriate and effective manner.

##### Section 1717.1

The proposed changes clearly establish a pharmacy's obligation to protect the confidentiality of patient medical information in common electronic prescription files. Such files provide patients with greater flexibility in the locations at which they can have their prescriptions filled but, absent adequate policies and procedures, could subject confidential patient information to unauthorized disclosure. The proposed language requires pharmacies to take affirmative steps to preserve patient privacy.

##### Section 1717.4

The proposed changes are designed to reduce the filling of fraudulent prescriptions. The question of a prescription's authenticity has been highlighted by the advent of electronic prescription systems, but the question of a prescription's authenticity is valid for all the different forms that a prescription may take. The proposed amendment would make the authenticity of a prescription and personal and professional obligation, thereby increasing the integrity of the prescribing process.

#### Section 1720

The proposed changes are designed to conform existing board processes to the examination changes established by Senate Bill 361 (Chapter 539, Statutes of 2003). The new examination is offered continuously thereby eliminating the need for application cut-off dates. The proposed amendments also shorten the period of time to take the examination after applying and the time allowed to pay the licensure fee after qualifying for a pharmacist license to streamline board operations.

#### Section 1721

The proposed changes increase the penalties for dishonest conduct related to the pharmacist licensure examination. The new examination will be offered continuously on a nationwide basis which will provide more opportunities for violations of exam security which will be balanced by the more severe penalties.

#### Section 1723.1

The proposed changes eliminate reference to the exemptee examination because the board no longer requires an exemptee applicant to pass an examination to receive a license.

#### Section 1724

The proposed changes are designed to reflect the methodology for establishing passing grades used by the pharmacist licensure examination in accordance with accepted testing standards.

#### Section 1749

The proposed changes eliminate obsolete fees and incorporate fees for licensure as a pharmacy technician. Previously, the fee for pharmacy interns was included in Section 1793.5.

#### Section 1793

The proposed changes are technical in nature and intended to make the section easier to read.

#### Section 1793.1

The proposed changes are technical in nature and reflect a modest reorganization of provisions related to pharmacy technicians.

#### Section 1793.2

The proposed changes eliminate language that duplicates provisions in existing statute.

#### Section 1793.4

This section is repealed because Senate Bill 361 (Chapter 539, Statutes of 2003) establishes the requirements for licensure as a pharmacy technician.

#### Section 1793.5

The proposed changes are designed to conform existing board processes to changes related to pharmacy technicians established by Senate Bill 361 (Chapter 539, Statutes of 2003).

#### Section 1793.6

The proposed changes are designed to provide greater flexibility to the design of pharmacy technician training programs. This flexibility will allow training programs to be composed of theoretical and practical training in proportions that best prepare pharmacy technician trainees. The change will also streamline the processing of pharmacy technician applications received from graduates of technician training programs.

#### Section 1793.7

The proposed changes are technical in nature and reflect a modest reorganization of provisions related to pharmacy technicians.

#### Underlying Data

None.

#### Business Impact

This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the absence of testimony indicating adverse economic impact regarding these rulemaking proposals at the informational hearings held by the board.

#### Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

#### Consideration of Alternatives

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

# Attachment 2

18 March 2004

RECEIVED BY CALIF.  
BOARD OF PHARMACY  
2004 MAR 22 PM 1:11

Paul Riches  
California State Board of Pharmacy  
400 "R" Street, Suite 4070  
Sacramento, Ca . 95814

Re: Proposed Changes to 16CAC 1709.1 and 1793.3

Dear Sir:

In the past I have found that proposed regulatory changes are more nearly assumed fact. While contrary opinions may exist, usually little or no notice is taken. As a California pharmacist for 49 years and a Board staff member for nearly half that time, I have previously spoken to proposed regulatory changes. On one occasion I personally addressed the Board in opposition to a change which re-instated a practice, previously shown to be hazardous. The vote was taken, and the change passed, before I had returned to my seat. I have watched other changes occur and up to this point, have withheld comment. I have observed the enforcement program reduced to "Self-Assessments", pharmacy generated "Quality Assurance Programs" and the reduction of the inspection program. The continuing erosion of regulatory procedures does not seem consistent with the statutory mandate to protect the public

I cannot find any justification for allowing a "pharmacist-in-charge" to be responsible for more than one pharmacy. The term "in-charge" implies direct responsibility for the on-going operation of the premises. The proposed subsection (c) would allow a P-I-C to be in charge of two pharmacies, while subsection (d) precludes the same pharmacist from supervising a wholesaler, etc. I fail to see the reasoning here. The supervision of a wholesaler would be much less of a hazard to public safety than supervision of two pharmacies. Subsection (f) and (g) place the responsibility on the designated P-I-C, to determine safe practice of pharmacy under these conditions. My concern would be that this arrangement might not be as much in the public interest as it would be in the economic interest of the parties involved. The original limitation has been proven over time to be an effective means of affixing responsibility, and assuring adequate over-sight of pharmacy personnel. This change is not needed or appropriate.

The proposed amendment to 16CAC 1793.3 has similar problems. An open-ended approach to the number of ancillary personnel that a pharmacist may supervise is an invitation to disaster. Again, the pharmacist is held responsible for the determination. Subsection (c) and (d) serve no relevant purpose, except to place the burden upon the pharmacist. The Board has experience in assessing ratios of personnel, through experimental programs in the past. I do not recall any that were deemed successful. It would seem inappropriate to expect a practicing pharmacist to make such a judgment

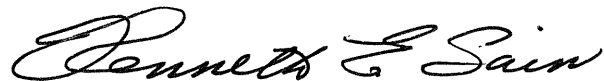
This type of thinking has engendered considerable anxiety on the part of many practicing pharmacists. The decisions required are charting a course in unknown waters. The practicing pharmacist no longer has the privilege of consulting with an Inspector. The economic advantage for HMOs and "closed-door" pharmacies is obvious. The benefit to the public is far less so. Any proposal that relaxes regulations concerning the actual participation of the pharmacist is disingenuous. By definition, regulations are designed to control or govern behavior. The responsibility of the enforcement staff is to assure compliance. The passing of regulations, that



are nothing but smoke and mirrors, defeats that purpose. Past Board members established regulations that adequately protected the public. In some instances these regulations did not seem a "good fit" for some segments of the industry. They did, however give specific guidance to the pharmacists and the enforcement was ensured by periodic inspections to assure understanding and compliance. In today's world the pharmacist cannot contact an inspector directly, buys his own law-book and seeks the advice of an attorney when troubled. As a consultant to several attorneys, I can assure you that most pharmacists today view their interaction with the Board as an adverse experience.

I would hope that the Board re-examines its present strategy and examines the process of regulation and enforcement in the light of that which best serves the public. The patient's welfare can best be served by pharmacists who are given specific guidelines, based on experience, along with adequate oversight from Board Inspectors. This can best be accomplished with staff who are themselves pharmacists, and are given the tools best suited to the job. This should not be confused with statutes or regulations that are based upon self-interests. Clearly, neither of these proposed regulations is in the public interest.

Sincerely,

A handwritten signature in cursive script that reads "Kenneth E. Sain". The signature is fluid and elegant, with the first name being the most prominent.

Kenneth E. Sain

1190 E. Palm St.  
Altadena, Ca. 91001